

8.14

## Notice of Allowability

### Application No.

08/704,445

### Examiner

Ram R. Shukla

### Applicant(s)

CHEN ET AL.

### Art Unit

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/17/03.
2. ☒ The allowed claim(s) is/are 41-59.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date 12/17/93.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 10/1/97
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Ram R. Shukla, Ph.D.  
Primary Examiner  
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### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shilpi Banerjee on 03-03-2004.

2. The application has been amended as follows:

#### **IN THE CLAIMS:**

Claim 41 has been rewritten as:

A method of reducing depletion of non-autologous hematopoietic cells in a mammal which lacks functional endogenous B- and T-cells, comprising administering to the mammal an effective amount of dichloromethylene diphosphonate such that the number of endogenous macrophages are decreased to a level effective to reduce depletion of transplanted non-autologous hematopoietic cells.

Claim 52 has been rewritten as:

A non-human mammal which lacks functional endogenous B- and T-cells, comprising human hematopoietic cells, wherein the non-human mammal contains a decreased level of endogenous macrophages sufficient to reduce depletion of non-autologous hematopoietic cells and wherein the decreased level of endogenous macrophages is achieved by administering to the mammal an effective amount of dichloromethylene diphosphonate.

Claim 56 has been rewritten as:

A method of improving or restoring engraftment efficiency for transplantation of a population of non-autologous hematopoietic cells in a host mammal which

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lacks functional endogenous B- and T-cells, comprising transplanting non-autologous hematopoietic cells into a mammal lacking functional endogenous B- and T-cells in conjunction with administering to the mammal an effective amount of dichloromethylene diphosphonate which decreases the number of endogenous macrophages in the host mammal, thereby improving or restoring the engraft efficiency for transplantation of said non-autologous hematopoietic cells.

IN THE SPECIFICATION:

"A-B" has been inserted in line 14 after "Figure 2" on page 4.

"A-B" has been inserted in line 22 after "Figure 3" on page 4.

3. The following is an examiner's statement of reasons for allowance:

The claimed invention is free of the prior art of record because the prior art of record does not teach or fairly suggest that selective depletion of macrophage would reduce depletion of anon-autologous hematopoietic cells administered to a mammal that lacks functional endogenous B- and T- cells. Additionally, the prior art of record does not teach or fairly suggest a non-human mammal which lacks functional endogenous B- and T-cells, comprising human hematopoietic cells wherein the non-human mammal contains a decreased level of endogenous macrophages sufficient to reduce depletion of non-autologous hematopoietic cells, wherein the decreased level of endogenous macrophages is achieved by administering to the mammal an effective amount of dichloromethylene diphosphonate.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

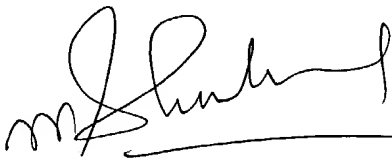
4. Examiner's Comments:

Applicants agreed to modify to scope of what was indicated as enabled in the office action of 5-12-1999 by the previous examiner, Examiner Hauda. Additionally, in the office action of 5-12-1999, any time art rejections were withdrawn and the subject matter that was free of the prior art of record was indicated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (571) 272-0548.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**